June 21, 2002

Evangeline Tsibris Cummings
Environmental Protection Agency
Office of Environmental Information
401 M Street, Northeast Mall, Room B607
Washington, DC 20460

Subject: Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (Attention Docket ID No. OEI-10014).

Dear Ms. Cummings:

Syngenta Crop Protection, Inc. is pleased to provide comments on the Subject Docket concerning the Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

Comments on Draft Guidelines

Overview, Scope, and Applicability

Syngenta Crop Protection completely supports the Congress and the Office of Management and Budget (OMB) in the effort to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, reproducibility, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies. Congressional intent of the Data Quality Act to provide a process for establishing the highest scientific standards for use and dissemination of information on study reviews, analytic results, risk assessments and in decision- and policy-making is a laudable goal

This information quality initiative is an outstanding way to further improve the scientific integrity of EPA regulatory actions and the quality of information relied upon and disseminated by EPA in the regulation of pesticides under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA) and other Agency statutes, including the Food Quality Protection Act (FQPA). We agree with the EPA statements that information quality is integral to the Agency's goals of protecting human health and safeguarding the environment.

Reflecting the need for improvement of the quality of information disseminated by the Federal Government to the public, Congress recently directed the Office of Management and Budget (OMB) to issue government-wide guidelines that *provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.* These guidelines must include mechanisms to allow the public to seed correction of disseminated information that does not comply with the information quality standards in the OMB standards

The U.S. Environmental Protection Agency (EPA, the Agency) Draft Guidelines were developed to comply with the U.S. Office of Management and Budget (OMB) Guidelines issued under the Information Dissemination requirements of the Paperwork Reduction

Act (PRA). 44 United States Code (U.S.C.) §§ 3504(d)(1); 3516 note. The PRA's Information Dissemination requirements are separate from the PRA's Collection of Information requirements. 44 U.S.C. §§ 3502(3),(12); 3504(c)(d); 3506(c)(d). An express purpose of the PRA's Information Dissemination requirements is *to improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society.*

With that in mind, the EPA draft document contains a large amount of preamble data called "Background and Discussion" which describes the Agency's current procedures for the quality of information disseminated and presumes that these are sufficient, perhaps with minor adjustments, to meet the mandates of the Data Quality Guidelines. While the assumption that the current procedures for ensuring data quality at EPA are sufficient to meet the standards of the data quality guidelines, there is not agreement in the regulated community that this is true. Syngenta is unable to determine what, if any, parts of the "Background and Discussion" will be utilized in the actual guidance (which begins on page 13 of the EPA draft document). The guidelines would be strengthened if revised to have most aspects of the preamble information integrated into the new guidance document. One example of this is Section 4.2 that addresses influential information and reproducibility which is not included in the draft guidelines per se.

In general throughout the EPA's draft guidelines there is generous utilization of potential exclusion criteria that allow the Agency to be quite arbitrary in its application of the Information Quality Guidelines. This is counterproductive to the spirit of the OMB Guidelines in that use of this draft guidance will mask the actual quality of the data used and the process for deciding whether to use or not use the guidelines will not be transparent.

Based on the above, Syngenta concludes that these draft guidelines, in their current form are fundamentally flawed and do not meet the requirements of the PRA to *promote the theme of improving the quality and use of information to strengthen agency decisionmaking and accountability and to maximize the benefit and utility of information created, collected, maintained, used, shared, disseminated, and retained by or for the Federal Government.*

1.1 <u>What is the purpose of these guidelines?</u>

Section 515 of the Treasury and General Government Appropriations Act directs the OMB to issue government-wide guidelines that provide policy and procedural guidance for federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by federal agencies. The congressional intent and purpose of these guidelines is to ensure that information meets basic information quality standards <u>prior</u> to dissemination by EPA. EPA's Internet capabilities for rapid public communication significantly increase the potential harm that can result from representation of findings, data, risk assessments, regulatory decisions, etc. as valid and accurate when in fact the information may not meet basic quality parameters of scientific reliability. EPA's draft guideline documents provide a great deal of background information on how the Agency currently ensures information integrity, how the information is managed and used, including a lengthy description of EPA's Agency-wide Quality System, the peer review process and policy,

and the Integrated Error Correction process. There is much less discussion on EPA procedures for ensuring that the disseminated information is determined to be scientifically accurate and credible as required by the Information Quality Guidelines. The Agency should revise the draft guidelines to contain a framework for revision of the current system to incorporate the new requirements as required by OMB.

Lines 402 – 403. The EPA states that these guidelines are not a *regulation*, are *not legally enforceable and do not create any legally binding requirements or obligations on EPA or the public*. The Agency should clarify that these guidelines are legislative rules that are promulgated under and implement the Information Dissemination requirements of the Paperwork Reduction Act (PRA)(44 U.S.C. §§ 3504(d)(1); 3516 note) and therefore are legally enforceable and create legally enforceable rights. Additionally, by contrast to the PRA's separate Collection of Information requirements, there are no statutory exemptions from any of the PRA's Information Dissemination requirements. The OMB's definition of disseminate is *to share with, or give access to, the public.* EPA's attempt to redefine this term contradicts congressional intent that this term be pervasive and all encompassing.

Lines 405 - 406. EPA states: *The guidelines may not pertain to a particular situation based on the circumstances, and EPA retains discretion to adopt approaches on a case-by-case basis that differ from the guidelines, where appropriate*. Syngenta questions this subjective approach which will undoubtedly leave the option to arbitrarily ignore the Information Quality Guidelines requirements. EPA cannot depart on a case-by-case basis from satisfying the data quality standards prescribed by the guidelines. To be clear and transparent the EPA should describe situations to which the guidelines would not apply and include examples of such.

Lines 410 - 412. EPA states: *The guidelines are a living document and may be revised periodically to reflect changes in EPA's approach or as we all learn more about how best to address, ensure and maximize information quality*. Syngenta advocates that any changes be published for Notice and Comment in the Federal Register as would be required since, as a part of the Administrative Procedures Act, changes are considered rulemaking. Revisions based on comments received should be made, followed by submission of the revised document to the OMB for review. The OMB should then review and approve any modifications/changes proposed by the Agency in a draft form prior to use of such revisions in any procedures.

1.2 When do these guidelines apply?

The EPA draft guidelines should be revised to contain a much more detailed framework and discussion on how it will ensure that disseminated information (which *will have or does have a clear and substantial impact on important public policies or important private sector decisions)* maximizes the requirements for quality, objectivity, utility and integrity. Currently there are much lengthier discussions on what is not covered by the guidelines, on the finite error correction process, and on the current Agency procedures already in place to ensure information quality. Unfortunately, and in particular with regard to actions taken under the Food Quality Protection Act (FQPA), the Agency's current procedures are often not in compliance with the Information Quality Guidelines as proposed by OMB. Syngenta submits that the congressional intent of these

Guidelines is to prevent the Agency's use of flawed, non-reproducible and outright erroneous information in study reviews, analyses, risk assessments and in decision- and policy-making processes well in advance of any dissemination of such to the public by any approach.

EPA should revise this section of the guidelines to include a listing of *influential information* which would be considered disseminated in "Top Agency Actions". Syngenta submits that data analyses and the underlying raw data, chemical information such as contained in the Integrated Risk Information System (IRIS), information relied upon for development of EPA policies, risk assessments and the guidelines/policies/-models used to conduct them should be included in such a list. A definition of "Top Agency Actions" would also be helpful to have in the guidelines.

Lines 422 - 423. Syngenta agrees with EPA's assessment that any "preliminary" information the Agency disseminates to the public is also considered "disseminated information" for the purposes of the guidelines and that "information" disseminated on the EPA's web site must comply with the Information Quality Guidelines. Additionally EPA should clarify that preliminary information includes preliminary risk assessments, interim risk assessments and/or reregistration eligibility documents (IRED), screening level (lower tier) assessments, etc. that would be disseminated by the Agency. Syngenta also submits that EPA should be clear with regard to the fact that any information made available prior to October 1, 2002 which remains on the website or in continued distribution and thus being constantly "redisseminated" after that date is subject to mandates of the Information Quality Guidelines and must be treated as such. Constantly "redisseminated" information is also subject to the Section 515 administrative mechanisms to address public complaints.

1.3 What is not covered by these guidelines?

Lines 451 - 452. The Draft Information Quality Guidelines state: *EPA may identify other materials that are not "information" for purposes of these guidelines*. Syngenta respectfully submits that this disclaimer completely contradicts congressional intent of these guidelines by leaving an option to arbitrarily ignore the quality of certain data simply by classifying it as *not information* for the purposes of these guidelines. EPA should revise the document to explicitly clarify intended inclusions/exclusion to ensure adherence to the intentions of the OMB guidelines and also provide examples of information that would be so classified.

Lines 458 through 461. EPA states *Information distributed only to government employees would not generally be covered by these guidelines because it is not directed to the public…These guidelines do not apply to intra- or inter-agency use or sharing of governments information*. Syngenta questions how any harmonization of processes and methodology can be vetted in the governmental scientific community if intra- and inter-agency distribution of information is not covered by the Information Quality Guidelines. For example, ongoing efforts in the harmonization of risk assessment processes between the Office of Pesticide Programs' (OPP) Environmental Fate and Effects Divisions (EFED) and the Office of Water should be subject to requirements of the Information Quality Guidelines . Another example is harmonization of data evaluation processes, risk

assessment procedures and sharing of reviews among the EPA, the California Department of Pesticide Registration, and the Canadian Pest Management Regulatory Agency (PMRA). The intra- and inter-agency documents shared in these efforts must be governed by the Information Quality Guidelines with regard to scientific quality.

Indeed, in Section 3.5 of the draft guidance the Agency states EPA plans to work with the States and other governments, the scientific and technical community and other interested data providers to develop and publish factors that EPA would use to assess the quality of this type information. This statement implies that the Agency will actually share intra- or inter-agency information with other stakeholders. EPA should define in the draft guidelines how it will evaluate whether the guidelines have been met.

Lines 474 through 481. Often, correspondence from EPA to a "person" contains certain regulatory/policy decisions/actions based on scientific information and assessments. These decisions and their justification may be subject to the requirements of the Information Quality Guidelines. Additionally, correspondence to State or International Agencies has the potential to become public information. Syngenta submits that EPA should not make exceptions for correspondence that contains information based on scientific data or models for which data quality must yet be determined.

Lines 482 - 485. The EPA states: *Distribution of information in press releases and similar announcements: These guidelines do not apply to press releases, fact sheets, press conferences or similar communications in any medium that announce, support the announcement or give public notice of information EPA has disseminated elsewhere.* The dictionary definition of the term "fact" is "a piece of information presented as having objective reality; **In fact**: in truth: actually". How then can a Fact Sheet or other announcements be exempt from meeting the standards of Information Quality? This statement circumvents the intent of the Guidelines to maximize the quality, objectivity, utility, and integrity of information disseminated by the Agency and is completely devoid of credibility within the context of Information Quality Guidelines. The mere fact that the Agency has disseminated the information *elsewhere* does not guarantee that it meets the standards set by the Information Quality Guidelines. EPA should revise this section to establish a process for verification that items disseminated elsewhere have equaled or surpassed the standards required by the Information Quality Guidelines prior to use as press releases, fact sheets, press conferences, desk statements or similar communications in any medium

Lines 486 – 493. EPA states that *The guidelines do not apply to outdated or superseded EPA information that is provided as background information but no longer reflects EPA policy or influences EPA decisions where EPA indicates (in a disclaimer or otherwise) that the materials are provided as background materials and do not represent EPA's current view.* Syngenta submits that EPA should be clear with regard to the fact that any information made available prior to October 1, 2002 which remains on the website or is in continued distribution (redissemination) is subject to mandates of the Information Quality Guidelines. The draft guidelines should be revised to reflect situations when outdated or superseded information not meeting the data quality guidelines would be needed. EPA should consider a type of designation to flag the data requiring reassessment until such as been accomplished. EPA could also consider a type of

designation to show when data has been thoroughly evaluated under the Information Quality Guidelines.

Lines 522 through 527. Public filing example that would not fall under the Information Quality guidelines…..*information submitted by a participant in a voluntary program; and other information voluntarily provided to EPA by third parties, such as data, studies, analyses, and other types of comments or input.* Syngenta interprets this statement to include any information submitted voluntarily by registrants, or other stakeholders. This information would be in the form of studies or assessments conducted to influence or assist in FQPA evaluations, water monitoring done on a voluntary basis, probabilistic risk assessments, market basket studies conducted voluntarily, etc. If our interpretation is correct, this portion of the Draft Guidelines is not wholly acceptable under the Information Quality Guidelines and must be revised to define categories of data that will fall under its mandates. Dissemination of the information from certain voluntary submissions will clearly be data that has been generated in scientific studies requiring adherence to the Information Quality Guidelines requirements. Other voluntary submissions, particularly those that may be generated by the issuance of a Notice and Comment period may not require portions of the data quality standards such as reproducibility. The Agency should revise the guidelines to include a clear framework for how it will conduct assessments of user information and other public filings that it may use in risk assessments or other regulatory decision making processes for applicability of the Information Quality Guidelines.

Line 545. EPA's Draft Guidance Document states: *EPA may identify other instances where information is not "disseminated" by EPA because EPA does not initiate or sponsor the distribution of information.* Again, Syngenta respectfully submits that this disclaimer completely contradicts the intent of the Guidelines by leaving an option to arbitrarily ignore the quality of certain data that EPA may use even though the Agency did not sponsor or originally distribute the information. EPA should revise the guidelines to outline a process to exert control over use of information that is not originally "disseminated" by EPA but was used by EPA or included as an EPA summary and must be subject to Information Quality Guidance criteria. EPA should under no circumstances redisseminate such information that does not meet the requirements of the Information Quality Guidelines .

1.4 What happens if information is not initially covered by these guidelines, but EPA subsequently disseminates it to the public?

Syngenta agrees with EPA in that adoption, endorsement or use of information not originally covered by the guidelines in any subsequent dissemination or distribution is then retroactively subject to the guidelines. However, EPA should clarify this in the draft guidelines to ensure that such information is subject to the guideline mandates prior to its adoption, endorsement or use by the Agency.

1.5 How does EPA ensure the objectivity, utility, and integrity of information that is not covered by these guidelines?

EPA should redefine its policy in the draft guidelines to reflect a basic standard of information quality that must be met by all of the information it distributes meets and that its utility, objectivity, and integrity is scaled and appropriate to the nature and timeliness of the planned and anticipated uses. There should be a clear description of the scaling factors and how they will be applied with regard to dissemination of any data that is deemed not covered by these guidelines.

Defining Information Quality

2.1 What is "quality" according to the guidelines? EPA needs to clearly define what is meant by "quality" and support with examples covering different types of information and data.

EPA should further clarify that objectivity, utility, integrity and repeatability are constituents of the encompassing term "quality". Additionally, EPA should clearly adopt the quality principles applied by Congress to the Safe Drinking Water Act amendments of 1996(42 U.S.C. § 300g1(b)(3)(A), (B)). Under that law an Agency is directed, "…to the degree an agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if reliability of the method and the nature of the decision justifies use of the data)." 42 U. S.C. § 300g-1(b)(3)(A).

Ensuring and Maximizing Information Quality

3.1 How does EPA ensure and maximize the quality of disseminated information?

This Section of the draft guidelines should be revised to contain a framework for revision of the EPA's current fragmented and inconsistent system to incorporate the new requirements as required by the Information Quality Guidelines . This section should contain a process to ensure that the quality of information with the potential for dissemination is evaluated well in advance of possible public access.

3.2 How does EPA define influential information for these guidelines?

It is unclear how the Agency will address "Influential information" since there is variation in the background information of the document (Lines 212 – 231) and the actual draft guideline description (Lines 589 – 628). EPA should redefine "influential" information in the draft guidelines as information relating to any decisions or policy matters that must be supported by quality information made available in the item being disseminated and/or underlying data or analytical results that can be reproduced consistent with the OMB guidelines. Classification of information as "Influential" or "Not Influential" must occur when the data are reviewed or during the risk assessment process since the Information Quality Guidelines must be applied during evaluation of the information, not only when the dissemination stage is reached.

EPA has redefined the term "Influential Information" from OMB's definition in the Information Quality Guidelines . EPA's draft guidelines expand on OMB's definition of "Influential Information" but then negate any rigor afforded by the expanded definition by inserting the "Case-by-Case" situation that gives the Agency (not an external or independent party) the right to determine what is "Influential Information". The Agency further deflates this provision by placing subjective terms such as "acceptable", "*degree* of rigor", "*extent* practicable", etc. in the discussion on "influential information". Additionally the Agency's draft guidelines indicate that "original and supporting data may not be subject to the high and specific degree of transparency required of analytical results". Evaluation of analytical results analytical results without knowledge of the manner in which the analytical results were obtained and the quality of the original and supporting data, especially in the case where statistical methodology may be in question does not follow OMB guidance for transparency.

"Influential Information" must include information on all influential aspects of regulatory decision-making such as Environmental Fate and Effects, Environmental Risk Assessment, endangered species assessments, etc. The EPA Draft Guideline definition currently only applies to "human health", however the EPA routinely makes significant regulatory decision on other types of risk that OMB clearly intended to be covered in the Information Quality Guidelines . The Agency should revise the draft guidelines accordingly.

3.3 How does EPA ensure and maximize the quality of "influential" information?

First EPA should clearly adopt the quality principles applied by Congress to the Safe Drinking Water Act amendments of 1996 (42 U.S.C. § 300g1(b)(3)(A), (B)). Under that law an Agency is directed, "to the degree an agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if reliability of the method and the nature of the decision justifies use of the data)." 42 U. S.C. § 300g-1(b)(3)(A). The Agency should also define clearly where and why the SDWA amendments require "adaptation" (as opposed to complete "adoption") and what that "adaptation" will include.

Syngenta submits that in addition to the four parameters listed to ensure maximization of quality for "influential" information with regard to reproducibility of analytical results, there are several other factors required for a high degree of transparency. In addition to: 1) original source of data used, 2) various assumptions employed, 3) analytical methods applied, and 4) statistical procedures employed, EPA should be required to add: 5) the protocol(s) used to generate the data and the approval mechanism at the Agency, 6) information on reproducibility, 7) scientific justification for each (various) assumption used, 8) scientific justification for each of the analytical methods applied, 9) scientific justification for the statistical procedure used. EPA should also use validated studies that have been determined to have significance on the analytical results and risk assessments, and should supply the original and supporting data. If there are confidentiality issues with making the data available to the public, the agency must still disclose the specific

quantitative methods and assumptions that have been employed to ensure robustness. EPA should under no circumstances use data that the Agency itself cannot access due to confidentiality issues.

The draft guidelines state that EPA has several Agency-wide and Program- and Region-specific policies and processes which the Agency applies to ensure and maximize the quality of influential information. This suggests that the guidelines need only rely on the assumption that current Agency procedures for ensuring and maximizing information quality are adequate to comply with the mandates of the Information Quality Guidelines Syngenta disagrees with this premise and notes, as an example of the failure of the current procedures, the new requirements for endocrine disruption testing based primarily on results from a study conducted at Tulane University which were not reproducible and ultimately based on falsified data. EPA's current Quality System, including the "EPA Quality Manual", the peer review process and Integrated Error Correction Process failed to identify that data from this study did not meet the standards of reproducibility. (See Discussion on Reproducibility).

3.4 <u>How does EPA ensure and maximize the quality of "influential" scientific risk assessment information?</u>

With regard to information about risks to human health, safety and the environment, the EPA should clearly "adopt" the quality principles applied by Congress to the Safe Drinking Water Act amendments of 1996(42 U.S.C. § 300g1(b)(3)(A), (B)). Under that law (SDWA) an Agency is directed, "to the degree an agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if reliability of the method and the nature of the decision justifies use of the data)." 42 U. S.C. § 300g-1(b)(3)(A). The draft guidelines should be revised to clearly include environmental fate and effects risk assessments be conducted under the principles of the SDWA by the October 1, 2002 finalization deadline.

The SDWA does not limit the best available peer-reviewed science only "as appropriate". EPA should eliminate this qualification as it suggests the arbitrary use of less rigorous standards. EPA should revise the guidelines to direct validation and reproducibility of studies. The guidelines should also provide a framework for the Agency to follow stating what the significance of the study measured endpoint or measured impact is on an evaluation, risk assessment, risk mitigation, or regulatory decision. Additionally, under the draft guidelines EPA should define "best available" to specify availability meaning at the time the risk assessment is disseminated, rather than at the time it is conducted. Otherwise if best "new" science became available between the time EPA proposes a regulation or remedial decision based on an older, now flawed assessment, the quality of the data and risk assessment(s) does not then meet the mandates of the Act.

The EPA should also revise the guidelines to adopt a *basic quality standard for dissemination of public information about risks of adverse health effects as intended by*

Congress under 42 U.S.C. § 300g-1(b)(3)(B). This revision should direct the Agency to ensure that the presentation of information effects is comprehensive, informative, and understandable. Further the guidelines should be revised to require documentation specifying "(i) each population addressed by any estimate of applicable risk effects, (ii) the expected risk or central estimate of risk for the specific populations affected, (iii) each appropriate upper-bound or lower-bound estimate of risk, (iv) each significant uncertainty identified in the process of the assessment of risk affects and the studies that would assist in resolving the uncertainty, and (v) peer-reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific data."

The standards of data quality and transparency apply to Agency analysis of a single study as well as to analyses that combine information from multiple studies, including risk assessments. The Agency should draft consistent standards for quality, validity, reproducibility and transparency used in generation of analytical results including the specific data used, the various assumptions employed, the specific analytical methods applied, and the statistical procedures employed for scientifically valid risk assessments. In cases where compelling interests such as confidentiality of data precludes dissemination of such, the Agency should draft a framework that describes how robustness checks will be used to ensure quality of the risk assessments.

In all cases the Agency guidelines should be revised to require disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions (including default inputs) that have been employed for the conduct of risk assessments. OMB clearly explains in its guidance that this will not only provide for prompt error correction but more importantly that the public will be able to clearly assess how much the Agency's analytic results hinge on the specific analytic choices it makes.

EPA should also revise the draft Information Quality Guidelines to include a process for determination of the Agency's performance in meeting the OMB guidelines for dissemination of information. This EPA process should be included in the yearly reporting to and monitored by the OMB.

3.5 Does EPA ensure and maximize the quality of information from external sources?

This Section is extremely vague regarding the actual steps the Agency will take to ensure information from external sources meets the mandates of the Information Quality Guidelines , including undefined "plans" to work with the States, other governments, the scientific and technical community and other interested data providers to develop and publish factors EPA would use to assess information quality.

Syngenta submits that this section should be revised to include a mechanism to ensure that information from external sources meets the guidelines for quality information. Further, if the Agency has plans in place to work with the States, other governments and even within the government then the draft guidelines must be rewritten to include intra-

or inter-agency use or sharing of governments information as covered by the Information Quality Guidelines .

Pre-dissemination Review

4.1 What are the administrative mechanisms for pre-dissemination reviews?

This section of the draft guidelines must also be revised to reflect a valid plan for pre-dissemination reviews which ensure that the OMB guidelines are being met by all those involved in developing or managing information dissemination projects and that they are accountable for compliance with the standards for pre-dissemination reviews. Additionally any new or unique procedures developed by offices and regions must be incorporated into the guidelines and submitted for Notice and Comment prior to submission for approval by OMB.

Correction of Information

5.1 What are EPA's Administrative Mechanisms for Affected Persons to Seek and Obtain Appropriate Correction of Information?

While Syngenta does not object to a centralized administrative mechanism for affected persons to seek and obtain appropriate information correction, this Section of the draft guidelines should be revised to outline the exact steps to be taken to address the correction request including recordkeeping. Additionally, the responsible individuals ("information owners") should be designated in the draft guidance for each office/program to ensure transparent accountability.

5.2 Who may request a correction of information from the Agency?

Syngenta agrees that the definition of affected persons is persons who may benefit or be harmed by the disseminated information, and submits that additional relevant information may be included in the correction request.

5.3 What Should be Included in a Request for Correction of Information?

Syngenta agrees with EPA's list of information required in a request for correction of information and submits that additional relevant information may be included in the correction request.

5.4 Will EPA consider all requests for correction of information?

Syngenta submits that this section of the draft guidelines must be revised to remove the number of subjective qualifications the Agency is able to arbitrarily use to excuse it from considering the information correction request.

Specifically, the draft guidelines should be revised to specifically outline a framework for administering the Information Quality Guidelines in a manner which would not require a duplicative or contradictory response.

The draft guidelines must be revised to remove the exclusion of consideration of information corrections from the situation in which a "mechanism to submit comments to the Agency is already provided." During the process to implement the FQPA, the Agency began using a step-wise process to accept comments on data, use information, consumption, deterministic and probabilistic risk assessments, etc. It is clear from the record on comments for numerous actions taken under the FQPA process, that scientifically valid comments that would have easily met or surpassed the Information Quality Guidelines, were often completely ignored by EPA. This arbitrary choice by the Agency to pick and choose comments is also true of comments made on specific rules during the rulemaking process.

EPA should revise the draft guidelines to include a framework to ensure that every effort is made to meet the Information Quality Guidelines prior to dissemination of information for comment and to outline a process for consideration of comments that adhere to the Information Quality Guidelines. EPA should revise the guidelines to direct validation and reproducibility of studies. The guidelines should also provide a framework for the Agency to follow stating what the significance of the study measured endpoint or measured impact is on an evaluation, risk assessment, risk mitigation, or regulatory decision, etc.

Additionally, comments submitted after a comment period should not be summarily excluded from the information correction process. Syngenta does not believe that it is congressional intent to exclude any quality information from the error correction process.

EPA should provide examples of when an "affected person" would <u>not</u> be considered "affected" for review and comment.

5.5 <u>How will EPA respond to a request for correction of information?</u>

EPA should revise this Section to include a specific step-by-step process for addressing individual information correction requests, including designation of the responsible individuals (by office and/or program) and a timetable for each step in the process.

5.6 <u>Will EPA reconsider its decision on a request for the correction of information?</u>

Syngenta agrees with the information requirements EPA has included in the draft guidelines for an appeal. EPA should also include a specific step-by-step process for addressing individual information correction request appeals, including designation of the responsible individuals (by office and/or program) and a timetable for each step in the process.

5.7 <u>How does EPA process requests for reconsideration of EPA decisions?</u>

Syngenta submits that the description in the draft guidelines for this process are imprecise and unclear. This section should be redrafted to include a distinct process for reconsideration of EPA decisions in a specific step-by-step process for addressing reconsideration of appeals, including designation of the responsible individuals (by office and/or program) and a timetable for each step in the process.

Additionally, Syngenta submits that if EPA has rejected an error correction claim, that use of the EPA officials to decide on the appeal is not an objective process. At least, the relevant program office should not be involved in this process. The executive panel should be comprised of members with no vested interest in the decision, politically or otherwise. This section of the draft document should be revised to describe the executive panel and the rationale for the selection. Syngenta submits that, perhaps with OMB oversight, this is an area that the Office of Science and Technology Policy could be used in the appeals process.

Request for Public Comments on the Following Questions

Influential Information

Influential information relating to any policy matters must be supported by quality information made available in the report being disseminated and/or underlying data or analytical results that can be reproduced consistent with the OMB guidelines. Classification of information as "Influential" or "Not Influential" must occur when the data is reviewed or during the risk assessment process since the Information Quality Guidelines must be applied during evaluation of the information, and prior to the dissemination stage.

1. Is this approach appropriate?

EPA has redefined the term "Influential Information" from OMB's definition in the Information Quality Guidelines . EPA's draft guidelines expand on OMB's definition of "Influential Information" but then negate any rigor afforded by the expanded definition by inserting the "Case-by-Case" situation which gives the Agency (not an external or independent party) the right to determine what is "Influential Information". The Agency further dilutes this provision by placing subjective terms such as "acceptable", "*degree* of rigor", "*extent* practicable", etc. in the discussion on "Influential Information". Additionally the Agency's draft guidelines indicate that "original and supporting data may not be subject to the high and specific degree of transparency required of analytical results". How can the analytical results be evaluated without knowledge of manner in which the analytical results were obtained and the quality of the original and supporting data, especially in the case where statistical methodology may be in question?

"Influential Information" must include information on all influential aspects of regulatory decision-making such as Environmental Fate and Effects, Environmental Risk Assessment, endangered species determinations, etc. The EPA Draft Guideline definition currently only applies to "human health", however the EPA routinely makes significant regulatory decision on other types of risk that OMB clearly intended to be covered in the Information Quality Guidelines.

Additionally, the Agency has created a loophole in designation of risk assessments as "Influential Information" by evaluating resource constraints, including "time" available. This is unacceptable and contrary to the intent of OMB's Information Quality Guidelines. Indeed risk assessments are the epitome of "Influential Information" and each risk assessment must be afforded the amount of time and scientific talent required to conduct a scientifically sound evaluation of the quality of all data and assumptions used to determine safety.

2.Is the scope of information too broad?

The scope of the Agency's ability to class certain studies/risk assessments as "Influential Information" in EPA's Draft Information Quality Guidelines is inappropriate when applied to the Office of Pesticide Programs. The basis for the scope of "Influential Information" should be on specific criteria rather being subject to an arbitrary decision based on the time/talent constraints *du jour*. Nor should Agency actions/assessments/-decisions, etc. be exempted from the Information Quality Guidelines based on the potential for an "adjudicative process" since that would effectively exempt virtually all EPA actions and decisions from the Information Quality Guidelines.

3. Are there other classes of information that should be included?

This development process for other classes of information is not currently outlined in the guidelines and should be fully outlined and sent out for review and comment prior to finalization. Science reviews from expert bodies such as the World Health Organization's International Agency for Research on Carcinogenicity (IARC) should be included. Additionally as other "classes" are developed and potentially added, these changes should be submitted in draft form for OMB/public review and comment prior to finalization of any new guideline revisions.

4. EPA intends to develop experience implementing its definition of influential information over the first year, and then potentially broaden it to incorporate other classes of information disseminated by EPA. Is this an appropriate approach and consistent with the goal to continually improve Agency information?

This is appropriate only if it is carried out in a transparent process that must be described in the draft guidelines. Agreement with developing experience with the definition of "Influential information" does not in Syngenta's view encompass a longer time period for adopting the SDWA for environmental and safety assessments, which are currently on an unacceptable longer timetable in the draft guidelines.

Reproducibility

1. What comments do you have on the Agency's approach to facilitating the reproducibility of influential information?

Syngenta submits that in addition to the four parameters listed to ensure reproducibility of analytical results, there are several other factors required for a high degree of transparency. In addition to: 1) original source of data used, 2) various assumptions employed, 3) analytical methods applied, and 4) statistical procedures employed, EPA should be required to add: 5) the protocol(s) used to generate the data and the approval mechanism at the Agency, 6) information on reproducibility, 7) scientific justification for each (various) assumption used, 8) scientific justification for each of the analytical methods applied, 9) scientific justification for the statistical procedure used and 10) validation. EPA should also use validated studies that have been determined to have significance on analytical results and risk assessments, and should supply the original and

supporting data. If there are confidentiality issues which would make the data unavailable to the public, the agency must still disclose the specific quantitative methods and assumptions that have been employed to ensure robustness. EPA should in no way use data that the Agency itself cannot access due to confidentiality issues.

An example of this very situation occurred in 1996, and subsequently legislation was passed to require additional testing of pesticides, based on research conducted at Tulane University which claimed that mixtures of pesticides disrupt hormone systems up to 1,600 times more than individual pesticides alone. Published in a peer reviewed journal (*Science*) the study received extensive publicity, but before independent scientists could test the Tulane results, Congress included in the Food Quality Protection Act of 1996 a mandate that the Environmental Protection Agency develop an endocrine disruption screening program for pesticides.

The Tulane study was supposedly peer reviewed, but by November 1996, four laboratories had tried but failed to replicate the Tulane findings - a highly unusual outcome in the controlled setting of laboratory research. In January 1997, Science printed a letter from scientists at the U.S. National Institute of Environmental Health Sciences, Texas A&M University and Duke University reporting the Tulane results could not be replicated. A month later, the highly regarded international science journal *Nature* published results from British researchers who could not replicate the Tulane finding. Additionally one of the researchers was found to have falsified data and thereby committed scientific misconduct. Yet this study, devoid of scientific quality survives in law, and the regulated community will continue to be required to adhere to more onerous testing procedures resulting in products becoming more expensive or not available at all, and the consumers are ultimately the ones to suffer. All for phantom protection from a nonexistent problem.

The Agency states in the Information Quality Guidelines that *EPA plans to draw heavily upon our existing quality assurance and peer review procedures*. Syngenta submits that while the Agency has many scientifically sound procedures in place, there are numerous areas which require improvement in order to meet the standards required by the Information Quality Guidelines. In this age of rapid communication scientific errors can spread and be considered valid very quickly. A study by Dr. John M. Budd et al. in the Journal of the American Medical Association evaluated 235 scientific journal articles that had been formally retracted for reproducibility failure, scientific misconduct, etc. Not necessarily surprising. However the interesting part of the study showed that these retracted articles continue to be cited in the scientific literature. The average retraction time was on average over two years, so it is not necessarily unusual to see citations within that time frame, however these researchers found that even after the retractions had been published, the flawed studies continued to be cited (2,034 times).

2. Is it appropriate for the influential scientific, financial, and statistical information EPA disseminates?

Syngenta is encouraged to see the EPA's statement in the draft guidelines that the Agency takes reproducibility of data and results very seriously and that there are plans to continue consultations with the scientific and technical communities on reproducibility. Reproducibility is the litmus test of most types of scientific studies. In order to register products, Syngenta must comply with stringent 40 CFR Part 158 study requirements which are conducted under specific protocols and in most cases are reproducible. On the other hand some types of data such as epidemiological studies may not be reproducible in that they have an excessive number of variables and confounding factors which only occur at the time of study conduct.

Because reproducibility testing takes time (as well as other resources), Syngenta encourages the EPA to curtail dissemination of results until data underlying those results are thoroughly reviewed, and until, if deemed appropriate, the study has been repeated and reproduced to the satisfaction of scientist who are leaders in the field.

3. What types of original or supporting data do you believe should or should not be subject to a reproducibility requirement given ethical, feasibility, or confidentiality restraints?

Data submitted by pesticide registrants is subject to the most rigorous standards. Guideline studies conducted under Good Laboratory Practice standards are under strict quality standards and are considered validated and reproducible. However, differences in study results can be found from differences in species/strains tested and dosing techniques among many other protocol variables. Analytical results are only as scientifically valid as the underlying data, therefore the data used to produce the analytical results should be subject to the requirements of the Information Quality Guidelines .

EPA should outline the critical information required to categorize data as "influential". Any influential data being used by the EPA for regulatory and policy decisions should be subject to the "Reproducibility" standard. Otherwise the public and regulated community will continue to be exposed to supposedly valid data that may indeed not be legitimate.

4. What suggestions do you have for performing and reporting robustness checks of influential analytic results in cases where public access to data and methods will not occur due to other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections?

If access to data and methodology be limited, or not occur at all, due to other compelling interests such as privacy, trade secrets, intellectual property or other confidentiality protections, the Agency guidelines state that the EPA "should" apply especially rigorous robustness checks to analytical results and document what checks were taken." Syngenta submits that the Agency guidelines should "require" these especially rigorous robustness checks and furthermore that these checks be conducted or at least reviewed and verified by a scientifically qualified, external, objective entity. This could potentially be housed under the OSTP with oversight from the OMB. Otherwise no apparent quality checks can be ascertained and affected stakeholders will continue to be forced to "guess" at the basis for Agency actions. This principle should also be applied to any models used by the Agency for risk assessments

5. In particular, how might such robustness checks be applied to third party data that are used in analyses included in influential scientific, financial, and statistical information disseminated by EPA?

Data:

If EPA uses, relies on, cites as supporting a decision, agrees with or endorses third party data or analyses, the same stringent quality standards used for registrant and Agency generated data should apply to third party generated data. Third party data/analytical results/assessments must be scientifically reviewed very carefully and must be reproducible prior to use in Agency decision-making whether that be specific regulatory action, rulemaking, establishment of policy or other Agency actions.

Information from third parties has been used in the past by the Agency to make sweeping, precedent setting decisions and findings that often translate into additional (potentially unnecessary) study requirements for the most regulated community, the pesticide registrants. The EPA should design and include in the guidelines a process for ensuring the data underlying any analyses meet the standards of the Information Quality Guidelines.

Models:

The first step in application of the Information Quality Guidelines to models used by EPA is to make a determination that the model is scientifically validated. Models such as those used in development of aggregate and cumulative risk or others used in Environmental or Ecological risk assessments should all be non-proprietary and available for use in transparent risk assessment processes. As long as the model(s) are held as third-party proprietary entities they cannot be evaluated for reproducibility as required by the Information Quality Guidelines Additionally, the values used as input parameters (including any default values) in these models must also meet the standards of the Information Quality Guidelines including rigorous evaluation of scientific suitability for the purpose of the model.

Influential Risk Assessment

Human Health Risk Assessments

1. What suggestions do you have with respect to the EPA adaptation of SDWA principles for influential scientific risk assessments regarding human health risks?

2. Do you think that an adaptation of the SDWA quality principles is appropriate for most influential scientific risk assessment regarding human health risks disseminated by EPA?

Appropriateness

In so much as the SDWA requires that the Administrator use the best available science and supporting studies conducted in accordance with sound and objective scientific practice, the SDWA principles are appropriate for influential scientific risk assessments. Additionally, use of potential exposure values based on real situations is a scientifically strong point of the SDWA assessments that EPA should adopt as opposed to most of the current exposure scenarios which do not represent reality.

Syngenta also submits that the description of scientific information as requiring "peer review" must be more clearly defined. Peer-review from the standpoint of publication in academic journals can vary widely from one journal to the next and does not offer the same transparency or scientific rigor which must be utilized by a regulatory body such as EPA to ensure the intent of the Information Quality Guidelines is upheld. The Office of Science and Technology Policy has an obligation to become an active part of EPA's peer-review process rather than solely an office to house the SAP/SAB. Selection of panel members for a scientific review should come from a completely objective entity within OSTP rather than from EPA/OPP administrative or political appointees. Creation of the OSTP under the National Science and Technology Policy, Organization, Priorities Act of 1976 (Public Law 94-282) authorizes OSTP to lead the interagency effort to develop and implement sound science and technology policies. EPA should revise the Draft Information Quality Guidelines to include a peer-review structure that could operate with OSTP/OMB oversight to ensure that the "disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance is accurate, reliable, and unbiased."

Suggestions for Adoption of SDWA Principles

Quality information must be used in not only "final" Agency assessments/decisions/-documents but also in those deemed "Preliminary". While it is prudent to have a review and comment period for preliminary risk assessments they should be at the highest tier possible and not disseminated prematurely at lower levels of refinement based on time/resource/talent constraints.

3. EPA has decided to adapt the SDWA quality principles in the future for environmental and safety risk assessments. What suggestions do you have for how EPA should address environmental and safety risk assessments?

4. How do you think EPA should adapt the SDWA principles, how would you suggest EPA address environmental and safety risk assessments in its quality guidelines?

Suggestions for "Adaptation" of SDWA Principles for Environmental Assessments

Environmental Fate, Effects and Risk Assessments must be included in the Agency Information Quality Guidelines to be finalized by October 1, 2002, since EPA routinely makes significant regulatory decisions based on Environmental Risk assessments and supporting data. These assessments therefore constitute "Influential Information".

EPA should "adopt" the SDWA principles for review of Influential Information in Environmental Fate and Effects area to include clarity on the risk assessment process including how the Agency intends to assure that environmental risk assessments are based on best available scientific data and methods. The data quality process developed by the Agency to address "risk assessments" should incorporate the review of all available studies and risk assessments that meet quality criteria including those conducted by pesticide registrants. The process must be transparent and provide reproducible results. There is an unacceptable lack of transparency in the methods, models and supporting information used for risk assessment including lack of transparency in the development of new methodologies. Model validation is also a critical step. Currently there are deterministic and/or probabilistic models (public and third-party) used in the Agency's Environmental assessments that have not been through an adequate, science based, validation process.

It is unclear how the Agency is selecting input parameters. Often EPA seems to arbitrarily select input parameters for Environmental Assessments, thus negating the "utility" and masking the "objectivity" of the data/information as required by the OMB Information Quality Guidelines. The Agency must also reveal how it is using models in a tiered risk assessment process.

Probabilistic Risk Assessment methodologies as recommended by the Ecological Committee of FIFRA Risk Assessment Methods (ECOFRAM) and EPA's own Scientific Advisory Panels (4/5-7/00 & 3/13-16/01) should be developed and adopted by EPA for Environmental Risk assessments. Guidance from ECOFRAM and the two SAP meetings: (http://www.epa.gov/scipoly/sap/2000/april/freportapril572000.pdf; http://www.epa.gov/scipoly/sap/2001/march/march132001.pdf) should be used to develop the guidance/science policy framework for conduct of probabilistic environmental risk assessments. For scientific transparency and stakeholder input, this could be accomplished in much the same way that policies have been developed to conduct aggregate and cumulative risk assessments under the Food Quality Protection Act.

Increasingly, higher tier risk assessments are required to support pesticide registration activities under FIFRA and FQPA and the tendency is for EPA to prepare risk assessments *ab initio* in house or via contractors. This results in potential problems from contractor or EPA staff's lack of familiarity with the intricacies of specific products and uses. Moreover, with this new OMB guidance, preparation of refined risk assessments, conducted in a timely manner to fully meet the standards of highest quality and rigor will be difficult at current EPA staffing levels. This potentially leads to sterile arguments between stakeholders and EPA about process and conduct rather than, for example, the ecological significance in terms of risk.

As a result, Syngenta recommends that registrants conduct additional studies and perform risk assessments for submission that meet the criteria necessary for compliance with Data Quality Guidelines. The problem formulation phase of the risk assessment will identify needs for additional studies and assessments that should be undertaken by the registrant to ensure that all areas of risk are adequately characterized. These studies would become submissible studies for review by the Agency for adherence to quality criteria and "best science" standards as well as the quality and thoroughness of the risk assessments.

By this approach, the onus of developing high quality risk assessments and supporting studies falls to stakeholders while EPA staff are freed to use their reviewing experience to fully consider, evaluate and use the supplied information. EPA would retain the right to accept and reject the studies, request additional analyses and interpretations and also, Syngenta would commit to supply the underlying raw and derived data so that EPA can perform their own evaluations of model output etc.

Additionally this process has the advantage that registrants submitting risk assessments would submit a more complete package to support registration. This would minimize the need for additional resources and delays later in the process to address data gaps revealed by EPA while conducting risk assessments.

Sources of Information Disseminated by EPA

1. EPA would like you to suggest specific assessment factors that the Agency should consider using when assessing specific kinds of information submitted to EPA by outside sources, or information EPA obtains from outside sources.

Information that is not generated by EPA but is later disseminated by EPA in a publication or through a regulatory or policy decision should be evaluated for compliance with the Information Quality Guidelines requirements prior to use, much less dissemination, by the Agency long before any decision or dissemination process takes place.

Information that is generated through contracts, grants or cooperative agreements should be conducted under protocols and conditions that satisfy the requirements of the Information Quality Guidelines . Protocols and SOPs should be similar in scope and detail to those recognized and required to be followed for studies submitted by the regulated community.

Data generated under a statute, regulation, permit, order or other mandate is generally conducted under Good Laboratory Practice Standards for the Office of Pesticide Programs. However EPA should include in its Information Quality Guidelines a well-developed structure/mechanism for concordance and a unified approach to evaluation of data quality within and among the different EPA program areas.

The final category of information in this area is that submitted voluntarily to assist the Agency in its decision making process on a regulatory or policy determination. Since data generated to satisfy requirements of the Food Quality Protection Act has been submitted voluntarily (the data call-in process has, by and large, not been used) it would fall into this category. EPA states in the Draft Guidelines: *As an example, EPA may receive many studies concerning a particular issue. In evaluating the studies, EPA may not be able to rely on some of the studies submitted because EPA cannot determine that the quality and transparency of the data are sufficient for their intended use.* Syngenta agrees that the Agency should rely on studies for which a positive data quality determination cannot be made.

2. EPA also requests your input on how it should properly consult with the scientific and technical community in establishing these assessment factors.

The Agency states its intent to develop (with stakeholder input) and publish factors that EPA will use in the future to assess the quality of voluntary submissions or information that the Agency gathers for its own use. This type of input/consultation could be achieved in a number of ways. An EPA inter-program effort could be undertaken to develop the parameters required for information submitted on a voluntary basis. One requirement for conduct of new studies could be protocol approval by the Agency. It has been the industry's experience that study protocols are often submitted to EPA (OPPTS) but rarely actually approved with a signature and date. The Agency should have this process outlined and in place prior to October 1, 2002. An additional comment period at the time of publication of the factors will likely to be necessary.

Complaint Resolution

1. Specifically, what suggestions do you have regarding the receipt of the initial complaint through the Office of Environmental Information? Do you think a central point of entry is useful or problematic?

While Syngenta does not object to a centralized administrative mechanism process for affected persons to seek and obtain appropriate information correction, this Section of the draft guidelines should be revised to outline the exact steps to be taken to address the

correction request including record keeping (complaints and decisions). Additionally, the responsible agency member ("information owners") should be designated for each office/program so that responsibility is transparent in the EPA guidelines.

2. What are appropriate time periods for this process?

Despite OMB's statement that the administrative mechanisms are to allow the affected persons to obtain timely correction of non-compliant information, EPA has not addressed in even in a general manner the timeframe within which corrective action would be taken when a request is approved (while hard and fast standards cannot be expected given the range of information at issue, at least some general expectations would be helpful for more significant information); on the other hand, the Agency has stated, without regard to the importance of the information involved, that "it may elect not to correct some completed information products on a case-by-case basis due [solely] to Agency priorities, time constraints, or resources."

Syngenta submits that appropriate time period for the initial complaint process should be 30 days or less. Should the Agency fail to act in that time period, an automatic appeal process should be available.

Of more concern to Syngenta, is not the time for the complaint process, but designation of a timeframe for correction of the error(s) and further designation of a timeframe for correction of any downstream reviews, analyses, risk assessment, decision and/or policy errors, etc. resulting from the initial inaccuracy. There should also be an official mechanism in place to inform the interested public stakeholders of any substantive changes in Agency conclusions and recommendations, particularly with regard to human health assessments, made as a result of a complaint.

3. Once an appeal is submitted it would be decided by a top EPA official in collaboration with an executive panel. Do you think this is sufficiently objective and efficient to ensure a timely and appropriate response to an appeal?

Syngenta submits that if EPA has rejected an error correction claim that use of the Agency itself to decide on the appeal is not a process with objectivity. At least the relevant program office should not be involved in this process. The executive panel should be comprised of members with no vested interest in the decision, politically or otherwise. This section of the draft document should be revised to describe the executive panel and the rationale for the selection. Syngenta submits that this is an area that the Office of Science and Technology Policy could be used in the appeals process.

Conclusion

Syngenta proposes that EPA reconsider their proposed guidelines and ensure that the questions above are fully addressed. EPA should focus their efforts on how the data quality guidelines will be utilized and implemented to achieve data quality goals as stated in the OMB guidelines. EPA should also revise the draft Information Quality Guidelines to include a process for determination of the Agency's performance in meeting the OMB guidelines for dissemination of information. This process should be followed and included in the yearly reporting to OMB.

If there are questions regarding Syngenta's comments, please call Tim Pastoor at (336) 632-2226, Beth Carroll (336) 632-7178, or Tom Beidler at (336) 632-2976.

Sincerely,

Timothy Pastoor, Ph.D., D.A.B.T.

Global Head of Risk Assessment

Syngenta Crop Protection